



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10003, CMS-1771, CMS-R-244 and CMS-10744]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10003 Notice of Denial of Medical Coverage (or Payment)

CMS-1771 Emergency and Foreign Hospital Services and Supporting Regulation in 42 CFR
Section 424.103

CMS-R-244 Programs of All-Inclusive Care for the Elderly (PACE)

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit

reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title:* Notice of Denial of Medical Coverage (or Payment); *Use:* Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes.

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS-10003 (OMB Control Number: 0938-0829); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 937; *Number of Responses:* 16,191,812; *Total Annual Hours:* 2,697,556. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title:* Emergency and Foreign Hospital Services and Supporting Regulation in 42 CFR Section 424.103; *Use:* Section 1866 of the Social Security Act states that any provider of services shall be qualified to participate in the Medicare program and shall be eligible for payments under Medicare if it files an agreement with the Secretary to meet the conditions

outlined in this section of the Act. Section 1814 (d)(1) of the Social Security Act and 42 CFR 424.100, allows payment of Medicare benefits for a Medicare beneficiary to a nonparticipating hospital that does not have an agreement in effect with the Centers for Medicare and Medicaid Services. These payments can be made if such services were emergency services and if CMS would be required to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services provided by hospitals that do not have an agreement in effect under Section 1866 of the Social Security Act.

42 CFR 424.103 (b) requires that before a non-participating hospital may be paid for emergency services rendered to a Medicare beneficiary, a statement must be submitted that is sufficiently comprehensive to support that an emergency existed. Form CMS- 1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest that the hospitalization was required under the regulatory emergency definition (42 CFR 424.101 attached) and give clinical documentation to support the claim. A photocopy of the beneficiary's hospital records may be used in lieu of the CMS-1771 if the records contain all the information required by the form.; *Form Number*: CMS-1771 (OMB Control Number: 0938-0023); *Frequency*: Annually; *Affected Public*: Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents*: 100; *Number of Responses*: 200; *Total Annual Hours*: 50. (For policy questions regarding this collection contact Shauntari Cheely at 410-786-1818.)

3. *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Programs of All-Inclusive Care for the Elderly (PACE); *Use*: PACE is a pre-paid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to state standards. PACE programs must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon

approval of a PACE application, CMS executes a three-way program agreement with the applicant entity and the applicable state. With certain exceptions, this information collection addresses all operational components of the PACE program, as defined in 42 CFR part 460.

Form Number: CMS-R-244 (OMB control number: 0938–0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Business or other for profits and Not-for-profit institutions); *Number of Respondents:* 179; *Total Annual Responses:* 121,407; *Total Annual Hours:* 97,069. (For policy questions regarding this collection contact Lauren Brandow at 410-786-9765.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program – Contracting Forms; *Use:* Since 1989, Medicare has been paying for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) (other than customized items) using fee schedule amounts that are calculated for each item or category of DMEPOS identified by a Healthcare Common Procedure Coding System (HCPCS) code. Payments are based on the average DMEPOS supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office (GAO) and the Office of Inspector General (OIG) of the United States (U.S.) Department of Health and Human Services (HHS) have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DMEPOS. Due to reports of Medicare overpayment of DMEPOS, Congress required that the Centers for Medicare & Medicaid Services (CMS) conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999-2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after the successful competitive bidding demonstrations, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and mandated a phased-in approach to

implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). This statute specifically required the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the U.S. for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the Medicare DMEPOS Competitive Bidding Program (the Program).

CMS conducted its first round of bidding, Round 1, for the Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor (CBIC). CMS published a Request for Bids (RFB) and instructions for DMEPOS suppliers to submit their bids to participate in the Program. During this first round of bidding, DMEPOS suppliers from across the U.S. submitted bids to furnish competitively bid item(s) to Medicare beneficiaries residing or traveling to Round 1 CBAs. CMS evaluated these bids and contracted with those bidders that met all program requirements. Round 1 was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed the Program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the Program which included, but was not limited to: a delay of Round 1 (competition to begin in 2009) and Round 2 of the Program (competition to begin in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and Group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to bidders regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of MIPPA specified that the competition for national mail-order (NMO) items and services may be phased in after 2010. This section of MIPPA also specified that competitions to phase-in additional areas could occur after 2011. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The Affordable Care

Act (ACA), enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a NMO competition for diabetes testing supplies (DTS) at the same time as Round 2. The Round 2 and NMO DTS contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to recompete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except NMO DTS expired on December 31, 2013. (Round 1 Rebid contracts for NMO DTS ended on December 31, 2012.) The competition for the Round 1 Recompete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompete contract period expired on December 31, 2016. Round 1 2017 contracts were effective on January 1, 2017, and expired on December 31, 2018. Round 2 and NMO DTS contracts and prices expired on June 30, 2016. Round 2 Recompete and the NMO DTS Recompete contracts became effective on July 1, 2016, and expired on December 31, 2018.

On October 31, 2018, CMS issued a final rule (CMS-1691-F) requiring changes to bidding and pricing methodologies to be implemented under the next round of the Program. As a result, starting January 1, 2019, there was a temporary gap in the entire Program that lasted two years until December 31, 2020. When the program resumed in January 2021, CMS implemented a consolidated round of competition to include most Round 1 2017 and Round 2 Recompete CBAs for Round 2021. However, due to the 2019 novel coronavirus (COVID-19) pandemic, and the unexpected bid evaluation results, CMS only awarded Round 2021 contracts for two product categories: Off-The-Shelf (OTS) Back and OTS Knee Braces. As a result, this Paperwork Reduction Act (PRA) package reflects a significant reduction in burden, compared to previous packages, for Round 2021 which was implemented on January 1, 2021, and will concluded on December 31, 2023. This iteration of the package currently approved under OMB control number 0938-1408 is based on data from the first year of Round 2021

(January 1, 2021- December 31, 2021). *Form Number*: CMS-10744 (OMB control number: 0938–1408); *Frequency*: Occasionally; *Affected Public*: Private sector (Business or other for profits and Not-for-profit institutions); *Number of Respondents*: 179; *Total Annual Responses*: 121,407; *Total Annual Hours*: 97,069. (For policy questions regarding this collection contact Julia Howard at 410-786-845.)

Dated: August 2, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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